NOV 1 6 2004

510(k) Summary of Safety and Effectiveness

Orthofix Volar Distal Radial Plate

510(k) number K042766

1. General Information:

Proprietary Name	Orthofix Volar Distal Radial Plate
Common Name	Bone Plate
Regulatory Class	II
Device Classification	87HRS (21 CFR 888.3030)
Submitter	Orthofix Inc. 1720 Bray Central Drive McKinney, Texas 75069 USA 469-742-2500
Registration number	2183449
Contact Person	Nicolle L. Ferris Regulatory Affairs Specialist Phone 469-742-2578 Fax 469-742-2556
Summary Preparation Date	October 1, 2004

2. Description

The Volar Distal Radial Plate is an anatomically contoured, Delta-shaped plate intended for volar applications to the distal radius. The Plate features an angled head with two rows of holes for placement of screws and non-threaded pegs that will be placed distally on the radius to secure bone fragments and provide stabilization. If a bone graft is required, framed access to the site is made possible by the triangular opening in the plate that spans from the plate head to the distal portion of the shaft. The shaft of the Plate is placed proximally on the distal radius and it offers a variety of K-wire and screw placement options for secure fixation to the external surface of the bone. The

Plate provides the stabilization and fixation necessary in the treatment of distal radius fractures and osteotomies to allow early functional use of the hand.

The instruments that will be available with the Volar Distal Radial Plate and Bone Screws will include manual surgical instruments that will aid the surgeon in the application of the bone plate and insertion of the screws. Some examples of these instruments are pliers, multiple sizes of hex drivers, drill guides, and depth gauge. These instruments are considered by the Agency to be class I devices and exempt from 510(k) requirements.

3. Intended Use

The Orthofix Volar Distal Radial Plate is intended for the volar fixation of fractures and osteotomies involving the distal radius.

4. Predicate Device

The Orthofix Volar Distal Radial Plate is substantially equivalent in design, material, intended use, and function to two commercially available devices. The TriMed, Inc. Volar Bearing Plate, which was originally cleared by FDA under K040112 on March 12, 2004, and the Stryker Universal Distal Radius System which was originally cleared by FDA under K040022 on March 12, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

Ms. Nicole L. Ferris
Regulatory Affairs Specialist
Orthofix, Inc.
1720 Bray Central Drive
McKinney, Texas 75069

Re: K042766
Trade/Device Name: Orthofix Volar Distal Radial Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: October 1, 2004
Received: October 5, 2004

Dear Ms. Ferris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Orthofix Volar Distal Radial Plate

Indications for Use: The Orthofix Volar Distal Radial Plate is intended for the volar fixation of fractures and osteotomies involving the distal radius.

Prescription Use: X (Per 21 CFR 801.109) Or Over-The-Counter___ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042766